CALIFORNIA OPIOID MAINTENANCE PROVIDERS

January 27, 2015

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Re: Proposed California Amendment to Bridge to Health Reform Demonstration (No. 11-W-00193/9), Drug Medi-Cal Organized Delivery System Waiver

Objections of California Opioid Maintenance Providers [COMP] on Behalf of Beneficiaries and Providers of Services

Dear Ms. Garner, Ms. Hossain, and Ms. Lee:

We write on behalf of California Opioid Maintenance Providers (COMP) to oppose that portion of the California Bridge to Reform

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Demonstration (No. 11-W-00193/9) Amendment for Drug Medi-Cal Organized Delivery System Waiver, submitted by the California Department of Health Care Services on or about November 21, 2014, as it applies to medication assisted narcotic treatment programs, including methadone maintenance programs.

COMP opposes the waiver of beneficiary freedom of choice, statewideness, comparability, and reasonable promptness as proposed in the current waiver amendment application. If the waiver is approved, it will inevitably result in increases in opioid overdose, transmission of HIV and Hepatitis C, incarceration and premature death. The likelihood of such consequences was recognized by a federal court order in *Sobky v. Smoley*, a case brought in 1992 against California officials for delaying or denying access to Medicaid services by methadone maintenance patients. CMS should not, by granting a waiver, overturn the federal court injunction that remedied systemic violations of federal law and severe, indeed, life threatening hardship to medicaid beneficiaries.

Including narcotic treatment programs in the Organized Delivery System waiver is not necessary to achieve its goals. One of the principal objectives of the waiver application is a reformed residential treatment model by eliminating the restraints of the Institutes for Mental Diseases treatment limitations. This can be achieved without giving administrative control over narcotic treatment programs to 58 distinct California counties. COMP requests that CMS instruct the California Department of Health Care Services to remove narcotic treatment programs from the proposed waiver or deny the application in its present form.

COMP is a non-profit membership organization that represents 90% of the 140 licensed clinics providing methadone maintenance treatment for approximately 40,000 heroin and other opioid addicted people in California. COMP members provide statewide narcotic treatment program services that are unlike the services of other substance use disorder programs inasmuch as COMP members provide medication and psychosocial intervention to persons in treatment using licensed medical professionals, including physicians, physician assistants, and nurses. COMP provider members are highly regulated through a tiered system of local,

state, and federal regulatory agencies to ensure strict compliance with regulations and clinical best practices. COMP has actively participated in public policy development in California related to medication assisted treatment for opioid addiction for more than 25 years.

COMP members serve Medicaid beneficiaries through California's Drug Medi-Cal delivery system. Presently, under a system mandated by the permanent injunction entered by a United States District Court, the California Department of Health Care Services contracts for reimbursement with local counties who then contract with local providers. It contracts directly with providers when counties are unwilling or unable to do so.[1] Counties act as fiscal conduits and do not have ultimate contracting control of narcotic treatment programs. Reimbursement rates are set by the California Department of Health Care Services in accordance with a statewide rate setting formula prescribed by state law.[2] The delivery system is described in the State Plan approved by CMS. *See* SPA 14-038. The delivery system, developed as a result of the district court injunction, enabled California to achieve the largest statewide network of narcotic treatment programs in the United States, assuring access to critical life-saving medication assisted treatment to Medi-Cal beneficiaries in need of such services.

Under the current delivery system California is prohibited by the federal court injunction from denying or delaying narcotic treatment program services to Medi-Cal beneficiaries due to budgetary constraints. The injunction requires services to be delivered to beneficiaries with "reasonable promptness" as specified in 42 U.S.C. § 1396a(a)(8) and services must be equal in amount, duration, and scope, pursuant to 42 U.S.C. § 1396a(a)(10)(B).

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[1] *See Sobky v. Smoley*, United States District Court, Eastern District of California, Civ. No. S-92-613 (Judgment Entered February 3, 1995).

[2] *See* California Welfare & Institutions Code § 14021.51. *See also* California State Plan Amendment 09-22.

COMP opposes the proposed Drug Medi-Cal Organized Delivery System Waiver on behalf of its members and on behalf of the beneficiaries they now serve and will serve in the future. Given our members' decades of experience working with California counties and the Drug Medi-Cal program, COMP is certain that waiving provisions of the Medicaid Act relating to narcotic treatment program services will result in the return to the widespread denial or delay of vital medication assisted treatment to a very vulnerable and stimatized population that led to the federal court injunction, only this time without the protections and remedies available under the Medicaid Act which were invoked by the district court. This concern comes from actual experience, dating back to the time before the injunction, when many California counties that administered the drug treatment programs, routinely limited access to methadone treatment services. After twenty years of success, California's proposed Organized Delivery System would now give back primary responsibility to choose providers, to set rates, and to control access to narcotic treatment programs to California counties, including those that restricted the availability of Medicaid funded services prior to the injunction.

Because the Organized Delivery System would transfer control and ultimate contracting responsibility from the State to 58 different California counties, some beneficiaries suffering from opioid addiction will give up on obtaining treatment, and will burden the health care and criminal justice systems due to the collateral consequences of denial of timely treatment. Many beneficiaries are likely to overdose, contract HIV and/or HCV, go to prison, or die due to lack of medication and intervention and the adverse health consequences of addiction.

COMP has no position on application of the proposed waiver to other substance use treatment modalities.

Current Discussions with California DHCS

Beginning in December 2014, COMP and the California DHCS have participated in direct discussions of the current waiver application. California DHCS has represented that various changes in the proposed waiver application will be made and submitted to CMS. It has further represented that it will amend the

waiver application to address some of COMP's concerns. However, COMP has not yet been presented with a formal document indicating the exact changes California DHCS will propose to CMS. Because the CMS January 30, 2015 deadline for comments is imminent, COMP submits this letter based on the version of the waiver application circulated by California DHCS, which is posted for comment on the CMS website.

Direct discussions with California DHCS are continuing.

Existing California Law

There is no existing California legislation that authorizes the California Department of Health Care Services to seek an amendment to the Bridge to Reform Demonstration Project to create the Organized Delivery System.[3] In fact, California law specifies in considerable detail how Drug Medi-Cal services must be delivered to beneficiaries in narcotic treatment programs. That legislation is consistent with the current State Plan approved by CMS. It does not resemble the draft standard terms and conditions submitted in support of the Organized Delivery System. *See* Cal. Welfare & Institutions Code § 14124.24. Therefore, there is no assurance that the California Legislature will authorize implementation of the Organized Delivery System as it affects narcotic treatment programs, even if CMS ultimately grants a waiver of federal law.

The Federal Court Injunction

The *Sobky* lawsuit was filed because California counties limited Drug Medi-Cal beneficiary access to vital methadone maintenance services. Counties set limits on access due to budgetary constraints. Methadone maintenance was treated differently by the California Medi-Cal system than other medical services. Based

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[3] Cal. Welfare & Institutions Code § 140021.35 does provide authority to seek a waiver of federal Medicaid Act requirements. But this statute specifically references amendments to the State Plan and any necessary waivers to implement *only* existing section 14124.24.

on evidence submitted by the *Sobky* plaintiffs, and two years of litigation, district Judge David F. Levi first issued a preliminary injunction and then a permanent injunction against state officials. Judge Levi found:

> The key feature of California's drug abuse scheme is that services are administered through locally controlled community drug abuse programs, in which each individual county is vested with the discretion to determine the appropriate mix and level of drug abuse services needed in the community.

Sobky v. Smoley, 855 F. Supp. 1123, 1128 (E.D. Cal. 1994).[4] The court found that only 18 of 58 California counties provided funding for methadone maintenance services. *Id*. The court further found that:

> Plaintiffs have established that some methadone maintenance providers receive an insufficient number of treatment slots to serve all the Medi-Cal eligible in need of treatment; in response, some providers have created waiting lists for the Medi-Cal funded slots.

Id. at 1129. Plaintiffs also showed that some patients were unable to obtain services because of their county of residence.

> As a result, [some Medi-Cal beneficiaries] ... suffered consequences such as homelessness, exposure to disease, medical complications resulting in hospitalization, and the risk of probation revocation.

Id.

The court found that the methadone treatment services were not in effect statewide, violating 42 U.S.C. § 1396a(a)(1). *Id*. at 1136. The court further found

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[4] A copy of the *Sobky* district court opinion is submitted with these comments.

that all beneficiaries who were categorically needy did not receive medical services of equal amount, duration and scope. *Id*. The court also recognized that:

> For anyone in immediate need of medical treatment, the value of medical services provided in the future is less than the value of medical services provided when needed, particularly when the need is great.

Id. at 1142.

The district court held that the State system violated the "reasonable promptness" requirement found in 42 U.S.C. § 1396a(a)(8).

> The undisputed evidence in this case demonstrates that the insufficient funding by the State and counties of methadone maintenance treatment slots has caused providers of methadone maintenance to place eligible individuals on waiting lists for treatment. This is precisely the sort of state procedure the reasonable promptness provision is designed to prevent.

Id. at 1149.

The *Sobky* injunction was supplemented by a "Plan For Assuring the Availability of Methadone Maintenance Treatment Services."[5] The Plan was approved as a court order by the district court. It sets out the current delivery system of state and county contracts for providers and it assures that no beneficiaries will be denied services due to waiting lists. The remedial plan does not allow counties to control access to treatment. The Plan was approved as a court order by the district court and is incorporated in the final Judgment. The implementation plan is codified by California statute.

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[5] A copy of the Plan is submitted with these comments.

The *Sobky* injunction and the Plan remain in full force and effect today. Because the injunction is permanent, California officials would need to return to court to end the injunction in order to return administration to the counties.

The proposed waiver would turn back the clock more than twenty years if CMS agrees to waive 42 U.S.C. §§ 1396a(a)(1)(statewideness), 1396a(8)(reasonable promptness), and 1396a(a)(10)(B)(comparability), for medication assisted treatment. These statutes provide the legal underpinnings of the *Sobky* injunction and remedial Plan. CMS should not take any action that will overturn or undermine a federal court injunction that is based on proof of systemic violations of law and severe, life threatening, hardship to medicaid beneficiaries.

The Stigma Facing Medication Assisted Treatment

Substance use disorders, especially drug addiction, carry a stigma.[6] There is an uninformed belief that drug addicts are not deserving of scarce government resources and that methadone treatment simply substitutes one drug for another.[7]

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[6] "Stigma associated with drug addiction and use is strong and often structurally reinforced by government policies that contribute to its widespread acceptability." Earnshaw, Smith, and Copenhaver, *Drug Addiction Stigma in the Context of Methadone Maintenance Therapy: An Investigation into Understudied Sources of Stigma*, Int J Ment Health Addict. 2013 February 1. "Prejudice involves negative emotions and feelings held towards people who have been addicted to drugs. Prejudice towards injection drug users is associated with several personality traits (e.g., conservatism, religious fundamentalism), and higher perceptions of drug use as controllable (Brener & von Hippel, 2008). For example, healthcare workers who view drug use as 'controllable' were found to have greater prejudicial attitudes towards injection drug users (Brener et al. 2010)." *Id*. at 2.

[7] See Institute of Medicine, *Regulating Methadone Treatment (1995)*, at 29-30.

> With respect to public opinion, a substantial segment of public opinion over the years has opposed the use of methadone for the treatment of opiate addiction, and another segment is ambivalent about its use. Public attitudes toward addiction of any type, but particularly heroin addiction, are overwhelmingly negative. The debate over the extent to which addiction is a disease or a moral failure remains unsettled in the public mind. The stereotypes of addicts are of individuals engaged in criminal activity, predatory toward others, and unable or unwilling to respect the norms of acceptable social behavior or participate in the work force. The public's fear of opiate addicts creates a reluctance to spend "treatment" dollars on them; it also creates sympathy for a criminal justice response.

Institute of Medicine, *Federal Regulation of Methadone Treatment* at 29.

Although there is abundant professional, medical, and scientific research showing that these superstitions are not true, many decisionmakers, including county decisionmakers in California and elsewhere, do believe them to be true and act on their uninformed beliefs.[8] *See, e.g., A Helping Hand, LLC v. Baltimore County,* 515 F.3d 356, 359-361 (4th Cir. 2008); *New Directions Treatment Services v. City of Reading*, 490 F.3d 293, 306-307 (3rd Cir. 2007); *MX Group, Inc. v. City of Covington*, 293 F.3d 326, 342 (6th Cir. 2002) ("based on fear and stereotypes, residents believed that the drug addiction impairment of Plaintiff's potential clients, at the very least, limited the major life activity of productive social functioning, as their status as recovering drug addicts was consistently equated with criminality."); *Bay Area Addiction Research and Treatment v. City of Antioch*, 179 F.3d 725 (9th Cir. 1999).

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[8] Fresno County filed a motion to intervene in the *Sobky* case, seeking to challenge the injunction. Other counties, including Imperial, Orange, and San Diego counties, refused to administer the Drug Medi-Cal program at all. Some small, rural counties did not have the capability to administer the Drug Medi-Cal program and therefore turned to the State to do so.

The reality is that stereotypes, fear, and speculation will affect county control of narcotic treatment programs and administration of the Drug Medi-Cal system.[9]

County Resistance to Medication Assisted Treatment

As of July 2010, 18 of 58 California counties refused or were unable to administer contracts with some or all Drug Medi-Cal providers operating in their counties. Many counties that do administer the program, regularly impose barriers to access such as efforts to reduce funding, limit slots or oppose new locations.

County resistance is related to several factors. Some county governing bodies (Boards of Supervisors) and behavioral health administrators are philosophically opposed to treating opioid addiction with methadone. COMP has presented specific examples of county interference with and resistance to methadone providers to the Department of Health Care Services (DHCS).

Counties that do contract with Drug Medi-Cal providers use a variety of contracts, often supplementing state requirements and imposing their own county policies on Drug Medi-Cal providers. As a result, some providers who do business in different counties presently face inconsistent requirements, database issues, funding, and limitations that are not uniformly applied on a statewide basis.

At least one county, Yolo County (near Sacramento), publicly stated in 2007 that it was in the county's interest to have a provider contract directly with the State because (as required by federal law) counties must provide Drug Medi-Cal treatment to beneficiaries regardless of their county of residency. Yolo County determined that a provider might serve out of county residents, and that there was no benefit to Yolo County in administering a Drug Medi-Cal contract that included residents of other counties.

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[9] Former California Governor Schwarzenegger tried in 2010 to eliminate methadone from the Drug Medi-Cal program.

COMP is aware of specific examples of county interference with and resistance to methadone providers. For example, Aegis Medical Systems, Inc. [now Aegis Treatment Centers, LLC], a statewide provider of methadone maintenance services through the Drug Medi-Cal program, encountered differing database systems in many counties and found that many county billing systems were not HIPAA compliant. Contracting with those counties would expose Aegis' patients to privacy risks and Aegis to liability for data breaches. In 2007, Aegis ran into problems with Santa Barbara County. In that instance, the county imposed its own billing codes and erroneously declined to reimburse the provider for services it had provided to Drug Medi-Cal beneficiaries. The county also imposed its own billing requirements that impacted clinical treatment issues and operated a data system that was not HIPAA compliant.

Aegis had a similar experience starting in 2009 with San Bernardino County. The county was arbitrarily denying reimbursements due to the use of an idiosyncratic database system, which was not HIPAA compliant that required manual upload of data and reimbursement requests. The county also frequently challenged patient eligibility. Further, San Bernardino delayed in processing a fiscal year 2008-09 contract amendment.

In 2013 Merced County refused to increase the amount of Aegis's contract so that it could serve more Drug Medi-Cal patients for whom methadone maintenance was medically necessary. This issue was resolved when the California Department of Alcohol and Drug Programs convinced the County to allow the increase. Aegis experienced a similar problem with Stanislaus County in 2010-2011, when the County initially refused to renew Aegis's Drug Medi-Cal contract at all and, instead, put the contract process out to bid by other providers.

In 2013 Bay Area Addiction Research and Treatment, Inc. encountered a serious delay in its expansion plan for providing services at its Bi-Valley clinic in Sacramento. Sacramento County refused to authorize an increase in the number of patients treated at the clinic despite the fact that the clinic was licensed to treat the increased patients. The impasse was later resolved through intervention by the

California Department of Health Care Services after considerable delay and dozens of patients were denied access to treatment.

Similarly, Sacramento County denied an increase to CORE, a Drug Medi-Cal provider, due to budgetary considerations. The delay lasted about three months. During that time new intakes were delayed due to a growing waiting list. When slots became available there were many "no shows" and many patients on the waiting lists could not be contacted due to disconnected phones or they were no longer interested in obtaining treatment.

In 2013 Solano County denied a slot increase to Medmark Services, Inc. for treatment at its Vallejo clinic. Medmark was required to reduce the treatment capacity at one of its other Solano County clinics in order to meet the demand in Vallejo.

In January 2014 Tulare County denied Addiction Research and Treatment, Inc., an increase for Drug Medi-Cal patients, asserting that "[a]t the present time, Tulare County is not approving any increases to slots or Drug Medi-Cal."

As recently as January 2015 a Placer County official told Aegis that the county had made the decision to "opt-in" to a new system that requires all new patients to be screened by the county prior to entering a methadone clinic. Thus, medicaid beneficiaries who make the difficult and often tentative decision to end dependence on opioids would need to travel to a county clinic, potentially wait several days, and be screened before they could enter treatment. The likelihood is that potential new patients would never make it to a methadone clinic due to the delay.

Even with the *Sobky v. Smoley* injunction, the remedial Plan, and state control and responsibility, many counties still resist methadone maintenance treatment or expansion under the Drug Medi-Cal program. If the present legal constraints on county control are diluted or diminished by a federal waiver, California will have a full patchwork system of 58 different funding and delivery systems for methadone maintenance treatment, each subject to local political

pressures founded on various levels of uniformed prejudice, stereotypes, and myths about narcotic treatment programs.

Given past history of county opposition, delay, and inconsistent policies, and current resistance, the situation is certain to get worse. This will seriously affect prompt patient access to medically necessary treatment services, their free choice of providers, and the amount, duration, and scope of treatment.

Further, many patients will simply fall through the cracks as 58 counties attempt to construct and administer their own programs or join regional programs to fund and control the delivery of methadone maintenance treatment, resulting in overdose, disease, incarceration and the death of some patients from the denial or delay of treatment and the effects of opioid addiction.

Whenever there is a patchwork system for the delivery of treatment, patients suffer from lack of treatment or inconsistent treatment among the counties. In a recent survey conducted by the Health Access Foundation,[10] county administrators and/or county health departments responded to a series of questions about how they plan to respond to changes in financing and coverage under the Affordable Care Act going forward. The results of the survey indicate "a highly uneven safety net around the state." The Health Access report on the survey concluded "California will continue to have a highly variable patchwork of indigent care and safety-net programs and services. More critically, depending on upcoming decisions at the county level, in some counties consumers may have less access to care than before." In particular, California's 34 small, often rural, counties belonging to the County Medical Service Program (CMSP) consortium are contemplating cutting benefits like dental, vision, mental health and substance abuse. The authors also noted that information about each counties' programs is not readily available to policymakers, the press, or the public, explaining that

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[10] Health Access, "California's Uneven Safety Net: A Survey of County Health Care" (Nov. 2013). Available at http://www.health-access.org/item.asp?id=202.

counties "perhaps intentionally" do not publish the information on their websites or make it otherwise publicly available.

Likewise, the experience under California's Proposition 36, which allows referral of nonviolent drug offenders to supervised treatment instead of incarceration, shows inconsistent and often non-existent methadone maintenance treatment referrals among the counties. Although initially funded by the state, each county was required to develop its own plan for coordinating and administering services.[11] In other words, it was up to each individual county to determine what treatment services to make available to Prop 36 participants, much like the proposed Drug Medi-Cal Organized Delivery System.

The state discontinued funding in 2009, but the sentencing law remains in effect. The program was required to have an evaluation each year. Each year UCLA's Semel Institute for Neuroscience and Human Behavior conducted a study of Proposition 36 referrals, noting the following:

> The results showed positive outcomes for a significant proportion of participants in terms of drug treatment completion, reduced drug use and recidivism, and increased employment. However, opiate users did not enjoy the same positive outcomes.

The report attributed the poorer outcomes among Prop 36 opiate users to the limited use of narcotic treatment programs (NTPs), which includes methadone maintenance.

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[11] See "Substance Abuse and Crime Prevention Act of 2000: Analysis of FY 2004/05 Plans from the 58 Counties," by Health Systems Research, Inc., for the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration, and the California Department of Alcohol and Drug Programs (Sept. 12, 2005), available at http://www.adp.ca.gov/SACPA/P36_Reports.shtml.

Despite the acknowledgment as the best treatment for opioid dependence, very few Prop 36 opiate users receive placement in NTP. In fact,

> As has been reported in the previous Prop 36 evaluation reports, NTPs have been used infrequently in Prop 36. Very few Prop 36 opiate users receive placement in NTP. The use of NTPs in Prop 36 has decreased steadily over the past three years. In Fiscal Year 2005-06, 16.5% of Prop 36 opiate users received NTP, decreasing to 13.5% in 2006-07, and then down even further to 11.8% in 2007-08. Prop 36 opiate users who received NTP maintenance had the greatest reductions in their opiate use from treatment intake to discharge when compared to opiate users who received outpatient drug-free or non-NTP detoxification treatment. In contrast, across the same years, individuals seeking treatment for opioid use disorders outside of the criminal justice system received NTP between 75% and 85% of the time…Data from CalOMS indicate that, contrary to recommendations made by UCLA in previous reports to increase the use of NTPs, use of NTPs in Prop 36 is actually decreasing.

Thus, in this recent example of a county-managed "organized delivery system," referral to methadone maintenance was extremely limited. As a result, opioid-dependent participants had poor outcomes due to the services allowed by the county. All this despite the repeated recommendations of the research and evaluation team recommending stronger oversight and use of methadone treatment.

During the period from 2001 until 2009 in which Prop 36 was publicly funded, Western Pacific Med/Corp, which provides narcotic treatment services in Los Angeles, Orange, and Ventura counties, received a total of seven referrals throughout its ten facilities. Most other licensed NTPs received few to none.

Further Delegation of Administration and Funding Control Will Reduce Access to Treatment, Resulting in Denial and Delay

The historical experience with county administration and funding control has not been a good one for methadone treatment providers or for Drug Medi-Cal beneficiaries desperately in need of methadone maintenance treatment. Any further delegation of power to the 58 counties of California will result in more problems, undermining beneficiary access, statewide standards of funding and administration, and ultimately a failure to deliver critical medically necessary services to beneficiaries who seek to end their dependence on opioids.

- Counties will not want to or decline to cover out-of-county residents in violation of the federal Medicaid Act.

- Counties simply do not have the expertise and experience that the state has developed in administering, studying, and setting policy for drug treatment programs, especially narcotic treatment programs.[12]

- Many counties will not have the resources properly to administer the Drug Medi-Cal program, resulting in delays in treatment, denial of treatment, inconsistent policy, and some deaths.

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[12] Previously California had a separate Department of Alcohol and Drug Programs. This department administered the Drug Medi-Cal program under an interagency agreement with the California Department of Health Services. The Department of Alcohol and Drug Programs built up substantial expertise and experience. However, it was abolished and its functions have been absorbed by the California Department of Healthcare Services. Now, Healthcare Services seeks to delegate administrative and policy to the counties – the entities with the least expertise and the mostly likely to make uninformed decisions based on local political pressures.

- The cost of the Drug Medi-Cal program, and redundancy within the program, will likely increase if 58 counties provide an active third layer of control in addition to the federal government and the Department of Health Care Services.

- Breaches of federal and state confidentiality of patient identity, diagnosis and treatment, will occur if 58 counties are given power to make referral and funding decisions through coordination with other county agencies, such as police and sheriff's departments, or public health agencies. *See* 42 CFR Part 2, § 2.10 et seq.

- Counties will be buffeted by local political pressures to restrict, reduce, control access to, or eliminate methadone maintenance. This local political pressure will be particularly acute in small, rural counties where vocal advocacy, whether based on evidence or stereotyping, can be especially difficult to resist.

Given the historical record, there is no reason to believe county control over the funding and delivery of Drug Medi-Cal treatment to eligible beneficiaries will result in benefits to patients who seek to end their addiction. However, it is certain that county control will result in denial of treatment, delay in treatment, inconsistent standards of treatment, and ultimately increased emergency room visits, crime to feed the addiction, and the death of patients who cannot obtain services promptly. The proven consequences of eliminating federal access protections far outweigh any possible benefit asserted by the state.

Violation of the ADA and Principles of Parity

In addition to undermining the protection afforded Drug Medi-Cal beneficiaries by *Sobky*, the proposed Organized Delivery System is likely to license discrimination prohibited by the Americans with Disabilities Act because administration of the Organized Delivery System will differ among counties, while persons with other types of chronic illnesses and disabilities will not suffer such discrimination. The State and counties are covered entities under Title II of the ADA. 42 U.S.C. § 12131(1). Persons who seek drug treatment services are covered individuals with disabilities. 42 U.S.C. § 12210(c) ("Notwithstanding

subsection (a) of this section and section 12211(b)(3) of this subchapter, an individual shall not be denied health services, or services provided in connection with drug rehabilitation, on the basis of the current illegal use of drugs if the individual is otherwise entitled to such services."). Title II prohibits discrimination in the administration of public services, programs, and activities. 42 U.S.C. § 12132. *See* 28 CFR § 35.130(b)(1) ("A public entity, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of disability— ... (iii) Provide a qualified individual with a disability with an aid, benefit, or service that is not as effective in affording equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement as that provided to others").

The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) applies to the Organized Delivery System expansion population. The waiver would contravene the parity principles applicable the expansion population and to Medi-Cal beneficiaries receiving treatment through managed care organizations. Parity principles should therefore be applied to the entire population. These parity principles require substance abuse treatment benefits to be at parity with the benefits for other illnesses.[13] The limitations imposed, and the discretion conferred, on the counties with respect to benefits under the Organized Delivery System would be different from the Medi-Cal limitations and discretion with respect to other illnesses and diseases. In fact, the Organized Delivery System would carve out beneficiaries with substances use disorders for treatment that is different from other beneficiaries who do not suffer from such disorders, including preauthorization requirements and medical management standards.

[13] See section 1932(b)(8) of the Mental Health Parity and Addiction Equity Act of 2008

Narcotic Treatment Programs Should be Exempted from the Waiver

The Organized Delivery System will actually frustrate the objective of improving the selection of high quality providers and implementing evidence-based practices, given the long history of many California counties denying, delaying, and limiting services.

Current protections and provisions included in the draft standard terms and conditions of the Organized Delivery System waiver amendment are manifestly insufficient to substitute for requirements of the *Sobky* injunction and the substantive provisions of the Medicaid Act, particularly provisions regarding statewideness, reasonable promptness, comparability, and free choice of providers.

References below are based on the November 21, 2014 submission of Standard Terms and Conditions in Support of the Organized Delivery System amendment to the Bridge to Health Care Reform Waiver.

- Section 1. a. I. (p. 1) requires that beneficiaries reside in the county to receive benefits from a county that participates in the Organized Delivery System. This will cause a particular hardship and discourage many opioid users from seeking treatment in counties outside their residence. Methadone maintenance patients must receive medication every day and most must be physically present in a clinic to receive the medication. An opioid user temporarily staying in San Francisco will be unable to obtain treatment from a San Francisco narcotic treatment program if his or her residence is in neighboring Alameda, Marin, or San Mateo county. This is especially difficult for beneficiaries who live in one county but work in another. Frequently, it is most efficient to obtain treatment in the county where the beneficiary works in order that the beneficiary can receive treatment in a timely manner and maintain stability through daily medication treatment and weekly counseling. If this restriction, which presently does not exist, is implemented it will result in beneficiaries being forced to leave treatment outside their county of residence. Others will not be able to access treatment due to practical impediments for out of county treatment. Counties will likely give preferences to their own residents.

- Section 1.b. (p.2) further requires county residency.

- Section 1.d.i. (p.3) provides that eligibility determinations will be made by the county or county contracted provider. It further requires that county contractor determinations must be approved by the county prior to payment for services. Federal law currently governs admission to narcotic treatment services and establishes minimum criteria. This provision essentially sets up a treatment authorization system which is not applied or applicable to persons suffering from other chronic illnesses or diseases. It gives the county control over medical decisions.

- Section 1.e. I. (p. 3) sets no minimum standards for county internal grievance processes to challenge the denial of coverage for services or denial of payment for services. At present this process is deficient because there is no specificity to it, making it meaningless.

- Section 2.v. (p. 9) states that "The current reimbursement mechanisms for medication assisted treatment (MAT) will remain the same except for adding buprenorphine and disulfiram to the DMC waiver benefit for opt-in counties." This provision is vague and undefined because it fails to specify whether the rate setting methodology for narcotic treatment programs will be governed by current California law, or whether the reimbursement mechanism refers to the invoicing and payment process currently in effect in each county. The current funding mechanism, required by California statute,[14] assures adequate rates for ensuring provider participation, aligns payments with evidence-based practices, and provides incentives for efficiency in service delivery. It should stay the same and not be changed by the waiver.

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[14] *See* Cal. Welf. & Inst. Code 14021.51 ("Reimbursement for narcotic replacement therapy dosing and ancillary services provided by narcotic treatment programs shall be based on a per capita uniform statewide daily reimbursement rate for each individual patient, as established by the department.").

● Section 4.a. (p. 13) allows counties to select providers and contract with them. See also, section 4.a.iv. (p.14). Assuming a provider meets all federal and state criteria and is fully licensed and certified by the State as a Medi-Cal provider, this provision will violate the beneficiaries' right to free choice of providers and it will increase the likelihood that beneficiary access will be limited in counties in which the demand for services exceeds the capacity of providers selected by the county, despite the statement in section 4.a.ii. (p. 13) that "access cannot be limited in any way when counties select providers."

● Section 4.a.ii. (p. 13) states that counties must assure that all required services are available and accessible to enrollees of the DMC-ODS waiver program. However, the delegation of the control over access at the county level will for practical reasons, which we have set out in this letter, actually result in a decrease in access. Stigma, prejudice and discrimination are exceptionally powerful forces on the local level that will play a part in reducing access. Politically, many California counties will be unable to withstand local pressures that affect choice of providers, treatment modalities, and the distribution and use of state matching funds for narcotic treatment programs. **In addition, there is no provision for state oversight or any state preemption of county control when access is reduced. There is no objective measure of access and there is no description of who determines network adequacy and what metrics or measurements will be utilized for such a determination. In other words, the assurances in this section are simply words that will not have the desired practical effect, despite the requirement of a state approved remedial Plan, as set out in section 4.c. (p. 16).**

● Section 4.ii.(p.15) provides for an appeals process, but it is severely restricted. It only allows 10 days to submit the appeal. It only allows appeals when the reason given by a county is that the county already has an adequate network. This means that providers cannot appeal when the county discriminates or bases its decision on factors that are unstated, unknown, or based on pretextual issues unrelated to competence to provide narcotic treatment services. Further, the only remedy in the event the provider prevails by showing that the county does not have a sufficient network of providers is a "Corrective Action Plan." This allows for the

denial and delay of services to beneficiaries, who need daily medication, while the plan is formulated, approved or rejected, and implemented. For beneficiaries this means delay or denial of daily services. It means beneficiaries will not receive critical life-saving treatment when they need it, potentially resulting in overdose, disease, incarceration or death.

- Section 4.c. (p.16) requires counties to submit implementation plans, but there is nothing describing what the state will do, if anything, in the event an implementation plan is not effective or is not fully implemented.

- Section 4.d. (p. 16) states that State-County contracts will provide further detailed requirements. However, burying policy choices and requirements in contracts violates principles of transparency. It denies the public and stakeholders the opportunity to review and comment on policy that is made and implemented through the contracting process and it is subject to change without public review or input.[15]

- Section 5.a. (p.18) states that the state shall maintain a plan for oversight and monitoring providers and counties. But this provision does not provide specific elements of the plan and the monitoring and enforcement language that will put counties on notice of the standards the state will apply to them.

- Section 5. Timely Access (p.18) states that providers must meet standards for timely access, but it does not impose any requirements on the counties to see that narcotic program treatment is provided with reasonable promptness interpreted under federal law. It does not define "timely access," and does not say what, if anything, will occur if timely access is not provided.

- Section 7. Financing (p.20) says counties will propose county-specific rates and the State will approve the rates. This will affect access and result in

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[15] Promulgating policy through contracts also violates the California Administrative Procedure Act because policy provisions are standards of general application. See Cal. Gov. Code §§ 11340.5(a), 11342.600.

denial, delay, and limitation of services when rates are insufficient to attract sufficient providers to meet beneficiary needs and demands. There is no provision allowing or requiring a county to raise rates if necessary to attract additional providers. This provision will also result in unequal treatment of beneficiaries based on the rates paid in different counties and it treats substance use disorder patients differently than beneficiaries suffering from other illnesses and diseases.

COMP requests that narcotic treatment programs be exempted from the Organized Delivery System waiver for the following reasons.

First, narcotic treatment programs routinely suffer from public discrimination due to the stigma associated with opioid addiction. This stigma is a practical reality and is unlikely to change during the life of a federal waiver. By giving 58 California counties administrative control over narcotic treatment programs prejudice and discrimination will be inevitable, especially when county officials and administrators are subject to local political pressure.

Second, narcotic treatment programs are not subject to the problems currently identified with the Institutions for Mental Diseases exclusion, which is the principal impetus for the waiver application. Narcotic treatment programs do not provide residential treatment at all.

Third, narcotic treatment programs always employ evidence based practices in the treatment of substance use disorder due to the rigid licensing and regulatory requirements. These requirements are not imposed on any other substance use disorder modality. California narcotic treatment programs utilize a medical model for treatment, including on-site physicians, mid-level practitioners, nurses, and the administration of daily medication.

Fourth, recent issues involving lower quality providers and allegations of fraud among some California substance use treatment providers have not publicly included narcotic treatment programs. Narcotic treatment programs are regularly evaluated by county, state, federal and accreditation entities to assure compliance

with separate, rigorous standards in all areas of fiscal operations, quality of care, medication oversight, and facility safety.[16]

Fifth, California has implemented the requirements of 42 CFR 455.410 and 455.450 to screen and establish categorical risk levels for providers participating in the Drug Medi-Cal program. Pursuant to California Welfare & Institutions Code § 14043.75(b) the Department of Health Care Services has designated a high categorical risk level for newly certifying or newly enrolling Drug Medi-Cal providers and providers that submit an application for revalidation, except providers operated by government entities. The screening procedures were effective on September 22, 2014. Further, California has adopted an emergency regulation, with the full force and effect of state law, that governs program integrity in the Drug Medi-Cal Program. The Emergency regulation was readopted on December 22, 2014 and amends Cal. Code of Regs. § 51341.1.[17] Implementation of high risk screening and implementation of rules on program integrity make a federal waiver for the purpose of accountability and preventing fraud among narcotic treatment programs unnecessary.

If Narcotic Treatment Programs Are Not Exempted,
All Sobky *Protections Must Be Retained*

If narcotic treatment programs are not exempted from the waiver, then it is essential that all the protections afforded by the *Sobky* injunction and remedial Plan

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[16] The Institute of Medicine found in 1995 that "No other medication is so highly regulated." Institute of Medicine, *Federal Regulation of Methadone Treatment* (1995) 28.

[17] See Cal. Office of Administrative Law, DHCS-14-006E - Drug Medi-Cal Program Integrity. "The Department anticipates that the proposed regulatory amendments will enhance the fiscal integrity of the DMC program by curtailing and preventing provider fraud and abuse. More specifically, the amendments will enhance provider accountability and the Department's ability to enforce the requirements." DHCS-14-006E, Finding of Emergency at 3.

be included in the special terms and conditions of the waiver. These protections, as applied to the current structure of the proposed Organized Delivery System, include the following:

1. No waiver of the reasonable promptness requirement afforded by 42 U.S.C. § 1396a(a)(8);[18] [19]

2. No waiver of the comparability requirements among persons within the same medicaid categories, as afforded by 42 U.S.C. § 1396a(a)(10)(B);

3. No waiver of the statewideness requirement of 42 U.S.C. § 1396a(a)(1) in order to afford statewide standards and minimum administrative requirements governing county administration, including appeals by providers and beneficiaries.

4. No waiver of the free choice of providers requirement of 42 U.S.C. § 1396a(a)(23) in order to afford the beneficiaries the choice to pick their own providers just as other persons suffering other illnesses and diseases may choose their own providers.

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[18] An attachment to the California DHCS letter submitting the waiver amendment application for the Organized Delivery System, dated November 21, 2014, includes a section titled "Expenditure Authority." It numbers five pages. Pages four and five show the Title XIX Requirements that would not be applicable to the waiver. Requirement number one that would be waived is "reasonable promptness [section 1902(a)(8)]. Number two is "amount, duration and scope [section 1902(a)(10)(B)]."

[19] California DHCS officials have represented privately to COMP that the state does not intend a waiver of the reasonable promptness requirement. COMP requests an affirmative statement to that effect in any terms and conditions imposed by CMS so that there is no ambiguity.

5. Preserve beneficiaries' private rights of action to enforce sections (a)(1), (a)(8), (a)(10)(B), and (a)(23).

6. Strengthen state oversight, review, and approval of all county policies affecting the Drug Medi-Cal benefits available to narcotic treatment program beneficiaries, including oversight of all county decisions establishing county policies.

7. Preserve uniform statewide reimbursement fee for service rate setting methodology on a statewide basis for narcotic treatment providers, as presently exists pursuant to California state law. Cal. Welfare & Institutions Code § 14021.51. (COMP has no objection to county discretion to raise rates above a statewide minimum in order to attract sufficient providers.)

8. Prohibit expressly counties from taking any action or making any policies or decisions that result in waiting lists for treatment services due to budgetary or administrative constraints.

9. Establish an effective appeals process, giving providers and beneficiaries the right to appeal any county decision affecting denial, delay, availability, or administration of narcotic treatment program services to an impartial state official with the power to override the county decision. The time to submit an appeal must be no less than 30 days of the county decision and the appeal must be decided promptly. If the county action is overturned remedial steps must be taken promptly or the State must assume control.

10. Eliminate county power to select providers, so long as providers are fully licensed and certified by relevant state and federal entities.

11. Ensure that in all counties where narcotic treatment program services are available, they shall be available without regard to Medi-Cal beneficiaries' county of residence. Prohibit any policy or contract provision to the contrary. Create and implement a detailed process to assure that the cost of providing

services to out of county beneficiaries is covered and that there is no discrimination against out of county beneficiaries.

12. Establish a mechanism to supplant county administration promptly and completely if a county discriminates in any manner resulting in the denial, delay, or limitation of narcotic treatment program services.

COMP's Previous Participation in the Stakeholder Process

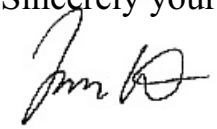
COMP previously discussed its concerns with California state officials. COMP has actively participated in each Waiver Advisory Group (WAG) meeting conducted by the Department of Health Care Services. COMP has submitted comments and data throughout the process.[20] COMP submitted comments on successive versions of the Draft Special Terms and Conditions for the Waiver Amendment.

[20] COMP is concerned that the minutes of the Waiver Advisory Group meetings fail accurately to reflect the content of the meetings because they do not fully include comments and concerns of persons who did not agree with the Department.

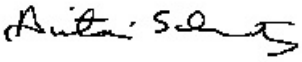
Attached are copies of letters and papers submitted by COMP to the Department of Health Care Services commenting on the proposed Organized Delivery System and proposed county payment mechanisms. Also attached is the district court's opinion in *Sobky v. Smoley*, the Judgment in *Sobky v. Smoley*, and the Plan for Assuring the Availability of Services, which was filed by state officials in response to the *Sobky* injunction.

Thank you for your attention and consideration.

Sincerely yours,



Jason Kletter, Ph.D.
President, California Opioid
Maintenance Providers



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